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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,030	02/11/2004	Samuel I. Stupp	8256	2190

22922 7590 06/20/2006

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,030	STUPP ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the response filed 2/23/06, claims 8-20 have been cancelled. Claims 1-7 remain pending.

✧

Claim 5 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites "said peptide ... comprises an RGD sequence". Use of the indefinite article ("an") implies that there is more than one RGD sequence. However, it is not clear what would constitute an RGD sequence other than RGD itself. In response to the foregoing, applicants have argued that the phrase "comprises an RGD sequence" means that there can be one RGD sequence, or there can be more than one RGD sequence. However, this does not answer the question. What would be an example of an RGD sequence other than RGD itself? For example, would applicants regard the tripeptide Phe-Leu-Asp as being an RGD sequence? What about Ser-Leu-Arg, or for that matter Asp-Gly-Arg...? It would help advance the dialog if applicants would provide at least one example of an "RGD sequence" other than Arg-Gly-Asp itself.

✧

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the

basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. §102(b) as being anticipated by Peterson (USP 5,733,868).

Peterson discloses (e.g., col 5, line 19+) compositions which comprise a polyamino acid and hydroxyapatite (col 5, line 31). The polyamino acid may be (cols 7-8) polylysine. Peterson does not use the term "nanotextured", but there is nothing in the instant claims to distinguish the composition on this basis.

In response to the foregoing, applicants have argued that because the reference does not recite the term "nanotextured", novelty is accrued thereby. However, applicants are not correct. Consider the following claims:

100. A composition comprising aspirin and water.

101. The composition according to claim 100, wherein the water is wet.

Applicants will no doubt agree that there are many references which disclose aspirin, and that there may be motivation to combine it with water. Where there may be

disagreement, however, is with regard to claim 101. Suppose that the examiner of claims 100-101 were to reject these claims over a reference disclosing aspirin, perhaps together with a second reference which discloses water as a pharmaceutically acceptable carrier. If that second reference did not explicitly state that "water is wet", it is the contention of this examiner that the rejection would be valid. It may be the case that applicants (of 10/777030) believe that if the examiner cannot produce a reference which discloses that "water is wet", he has not met his burden of demonstrating obviousness. It may be the case that some judges would agree with applicants on this point, but fortunately there are many more who would not.

Turning to the specifics of claim 1, the fact is that virtually all composites have a "texture" of some kind, and that they have a "microtexture" as well as a "nanotexture". The piece of paper on which this text is written is a composite that has a "texture" as well as a "microtexture" and a "nanotexture". If applicants have access to a microscope, it is suggested that they view a piece of paper therewith. Another example would be a human fingernail. This composite meets all of the following criteria: (a) it has a texture, (b) it has a "microtexture" (c) it has a "nanotexture" and (d) it is "biocompatible".

In traversing the foregoing, it would be helpful if applicants would provide a few examples of a composite which they believe has neither a texture nor a "nanotexture". If

applicants can do this, it will provide the basis for further discussion. But if not, it will leave the examiners position unrebutted.

The rejection is maintained.

✧

Claims 1-7 are rejected under 35 U.S.C. §102(b) as being anticipated by Stupp (USP 6,051,272).

Stupp discloses compositions which contain polylysine and calcium phosphate. Applicants have traversed by arguing that they are the first to discover that composite materials have a texture. However, applicants are not correct; the rejection is maintained.

✧

Claims 1-7 are rejected under 35 U.S.C. §102(a) as being anticipated by Gergely (*Key Engineering Materials* **240-242** (Bioceramics) 287-290, 2003)

Gergely discloses compositions which contain polylysine and calcium phosphate. Applicants have traversed by arguing that they are the first to discover that composite materials have a texture. However, applicants are not correct; the rejection is maintained.

✧

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a

person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-7 are rejected under 35 U.S.C. §103 as being unpatentable over Peterson (USP 5,733,868).

Peterson discloses (e.g., col 5, line 19+) compositions which comprise a polyamino acid and hydroxyapatite (col 5, line 31). The polyamino acid may be (cols 7-8) polylysine. Peterson does not use the term "nanotextured", but it would have been obvious to one of ordinary skill that composite materials have a texture.

Thus, the claims are rendered obvious.

✦

Claims 1-7 are rejected under 35 U.S.C. §103 as being unpatentable over Stupp (USP 6,051,272).

Stupp discloses compositions which contain polylysine and calcium phosphate.

Stupp does not use the term "nanotextured", but it would have been obvious to one of ordinary skill that composite materials have a texture.

Thus, the claims are rendered obvious.

✦

Claims 1-7 are rejected under 35 U.S.C. §103 as being unpatentable over Gergely (*Key Engineering Materials* **240-242** (Bioceramics) 287-290, 2003)

Gergely discloses compositions which contain polylysine and calcium phosphate. Gergely does not use the term "nanotextured", but it would have been obvious to one of ordinary skill that composite materials have a texture.

Thus, the claims are rendered obvious.

✦

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON, PH.D.
PRIMARY EXAMINER